K123444

COVIDIEN

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510(k) Summary

Date summary prepared: November 7, 2012

JAN 30 2013

510(k) Submitter/Holder

Covidien
5920 Longbow Drive
Boulder, CO 80301

Contact

Dawn D. Tindall
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Name of Device

Trade Name:	LigaSure Impact™ Curved, Large Jaw, Open Sealer / Divider
Catalog Number:	LF4318
Common Name:	Bipolar electrosurgical instrument
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR § 878.4400, class II, GEI).

Predicate Devices

The LigaSure Impact™ Curved, Large Jaw, Open Sealer / Divider was compared and found to be substantially equivalent to the following products of comparable type in commercial distribution:

Device Common Name: Bipolar electrosurgical instrument
Trade Name: Enseal G2 Tissue Sealer
Catalog Number: NSEALX22L
510(k) Number: K112033
Manufacturer: Ethicon Endo-Surgery, LLC

Device Common Name: Bipolar electrosurgical instrument
Trade Name: LigaSure Atlas, Tissue Fusion Open Instrument
Catalog Number: LS1020
510(k) Number: K010013
Manufacturer: Covidien

Device Common Name: ForceTriad Electrosurgical Generator; LigaSure Instruments
Trade Name: ForceTriad generator
510(k) Number: K070162
Manufacturer: Covidien

Device Description

The LigaSure Impact™, Curved, Large Jaw, Open Sealer/Divider (LF4318) is a sterile, single-use, hand-held bipolar electrosurgical instrument designed exclusively for use with the ForceTriad™ Energy Platform (cleared under K051644, K070162) to seal and divide vessels (including pulmonary) up to and including 7mm in diameter, tissue bundles, and lymphatics during open general surgical procedures. The ForceTriad's tissue-fusion

(LigaSure) mode is designed to deliver precise energy to tissue for a controlled time period to achieve complete and permanent tissue fusion.

The device combines the benefits of a long, curved jaw and a shaft-based jaw mechanism for improved access and visibility to critical structures. The pistol grip style handle was designed for improved comfort and usability, with an integrated hand switch and cutter for the subsequent sealing and dividing of tissue. Hand controls have been symmetrically placed to facilitate handling by both left and right-handed users. The LF4318 device connects to the ForceTriad energy platform with a 10 foot cord containing a LigaSure cable connector. This connector functions as a unique product identifier for device-specific recognition by the generator.

Intended Use

The LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider is a dedicated bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels is desired. The LigaSure Impact LF4318 is intended to be used with the ForceTriad energy platform to cut and seal vessels, and to cut, grasp and dissect tissue during surgery.

The indications for use include open procedures (general, urologic, vascular, thoracic, and gynecological) where ligation and division of vessels is performed. These procedures include vaginal hysterectomies, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The LigaSure Impact LF4318 can be used on vessels (arteries, veins, pulmonary vasculature, and lymph) up to and including 7mm and tissue bundles.

The LigaSure™ system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure system for these procedures.

Performance

The testing of the LF4318 involved extensive functional, bench and pre-clinical testing. The functional testing involved safety and performance testing in accordance with IEC 60601-1 and IEC 60601-2-2 and verification/comparative testing (to the predicate devices). The bench testing involved evaluation of the devices performance and ability to seal and divide vessels up to 7mm. The pre-clinical testing involved both acute and chronic testing evaluating the thermal spread and ability to achieve hemostasis of tissue and vessels in a variety of simulated clinical settings. The testing confirmed that the LF4318 is as safe and effective as the predicate devices and operated as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Covidien, Formerly ValleyLab, A Division of Tyco Healthcare
% Ms. Dawn Tindall
Senior Associate, Regulatory Affairs
5920 Longbow Drive
Boulder, Colorado 80301

January 30, 2013

Re: K123444
Trade/Device Name: LigaSure Impact™ Curved, Large Jaw, Open Sealer/Divider (LF4318)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: November 07, 2012
Received: November 08, 2012

Dear Ms. Tindall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K123444

Device Name: LigaSure Impact™ Curved, Large Jaw, Open Sealer / Divider (LF4318)

Indications for Use:

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Prescription Use X	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen

Digitally signed by Long H. Chen
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen, 0.9.2342.19200300.100.1.1=1300369056
Date: 2013.01.30 13:45:43 -05'00'

(Division Sign-Off)
Division of Surgical Devices
510(k) Number K123444